

Notice of Allowability

Application No.

10/646,371

Examiner

Nikita Wells

Applicant(s)

GRABER ET AL.

Art Unit

2881

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Personal Interview and Examiner's Amendment.
2. ☒ The allowed claim(s) is/are 1-30.
3. ☒ The drawings filed on 22 August 2003 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 012505
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 012505
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Nikita Wells
Primary Examiner
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Detailed Action

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on January 25, 2005, Dr. Michael J. Bastian requested an extension of time for 3 MONTH(S) and authorized the Director to charge Deposit Account No. 12-0080 (order No. SY9-179) the required fee of \$ \$1,020.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Examiner's amendment

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

A personal interview with the Applicant's attorneys, Dr. Michael J. Bastian and Mr. Andrew Karnakis, took place at the USPTO on January 25, 2005 (see attached Interview Summary) in order to insert allowable material into the independent claim 1 so that the application could be allowed. Following are the changes made to claim 1:

In claim 1, line 7, the following has been deleted: " , a mass spectrometric data based analysis,".

On line 9: after "on the analysis of" the following has been inserted: --at least one of the expression dependent based analysis and the search results based analysis of--.

Allowable Subject Matter

3. Claims 1-30 are allowed.

4. The following is an examiner's statement of reasons for allowance: ✓

The applicant's representatives demonstrated to the Examiner's satisfaction that, with respect to the newly amended independent claim 1 and the independent claims 16 and 28, the prior art of Vestal et al. (5,625,184) that was used for the 35 USC 102(b) rejection in the first office action, does not disclose the applicant's invention as shown below:

With respect to the independent claim 1, Vestal et al., as well as any other prior art, fail to disclose or make obvious, in combination with other recited features of the claim limitations, a method for analyzing a sample containing biomolecules comprising the steps of providing a plurality of sample portions of a sample containing biomolecules; acquiring one or more mass spectra of at least one of the sample portions; analyzing the one or more mass spectra using at least one of the expression dependent based analysis and the search results based analysis; selecting one or more mass-to-charge ratio ranges based on the analysis of the one or more mass spectra; and acquiring a fragmentation spectrum of at least one of the sample portions at one or more of the selected one or more mass-to-charge ratio ranges.

With respect to the independent claim 16, Vestal et al., as well as any other prior art, fail to disclose or make obvious, in combination with other recited features of the claim limitations, a method for analyzing a sample containing biomolecules comprising the steps of providing a plurality of sample portions each comprising a first sample containing at least one of peptides and proteins and a second sample containing at least one of peptides and proteins, at least a portion of the biomolecules in the first sample and the second sample being differentially labeled

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with an isotope coded reagent; acquiring one or more mass spectra of at least one of the sample portions; determining an expression level ratio between one or more differentially labeled biomolecules in the sample portion; and selecting one or more mass-to-charge ratio ranges based on the expression level ratios of a mass signal in the one or more mass spectra.

With respect to the independent claim 28, Vestal et al., as well as any other prior art, fail to disclose or make obvious, in combination with other recited features of the claim limitations, a method for analyzing a sample for at least one biomolecule comprising the steps processing at least a portion of the first vaporized ionized sample with a mass spectrometry apparatus to determine a first data set comprising a list of ion abundances as a function of ion mass-to-charge ratio of the first vaporized ionized sample; comparing the first data set with at least one of a second data set which identifies biomolecules by ion abundance as a function of ion mass-to-charge ratio; vaporizing at least another portion of the biological sample by matrix assisted laser desorption ionization (MALDI) to form a second vaporized ionized sample; and processing at least a portion of the second vaporized ionized sample with a mass spectrometry apparatus adjusted based on the first data set thereby to determine a third data set comprising a list of ion abundance as a function of ion mass-to-charge ratio of the second vaporized ionized sample.

The dependent claims 2-15, 17-27, and 29-30, are allowable by virtue of their dependence upon the independent claims 1, 16, and 28, respectively.

Conclusion

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita Wells whose telephone number is (571) 272-2484. The examiner can normally be reached on 8:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on (571) 272-2477. The central fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita Wells, Primary Examiner
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January 25, 2005